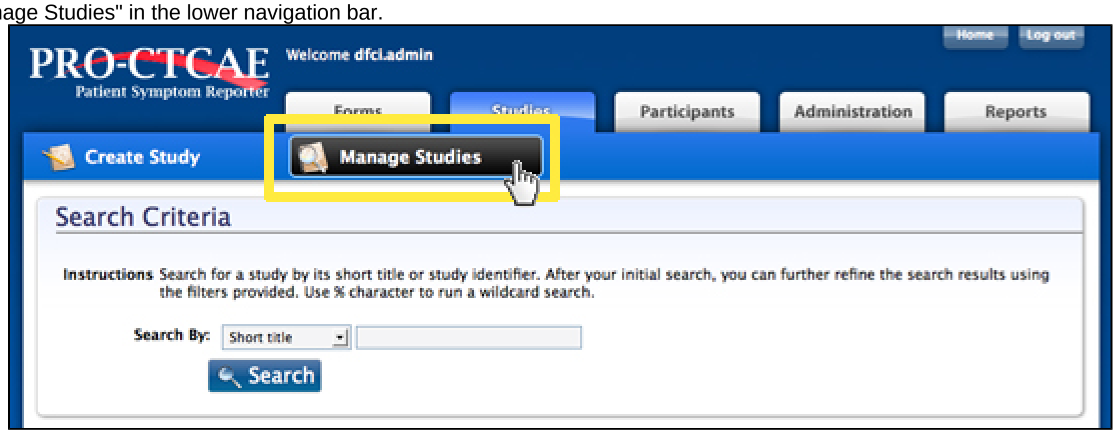
View-Edit Study

Manage Study Staff Studies

Important

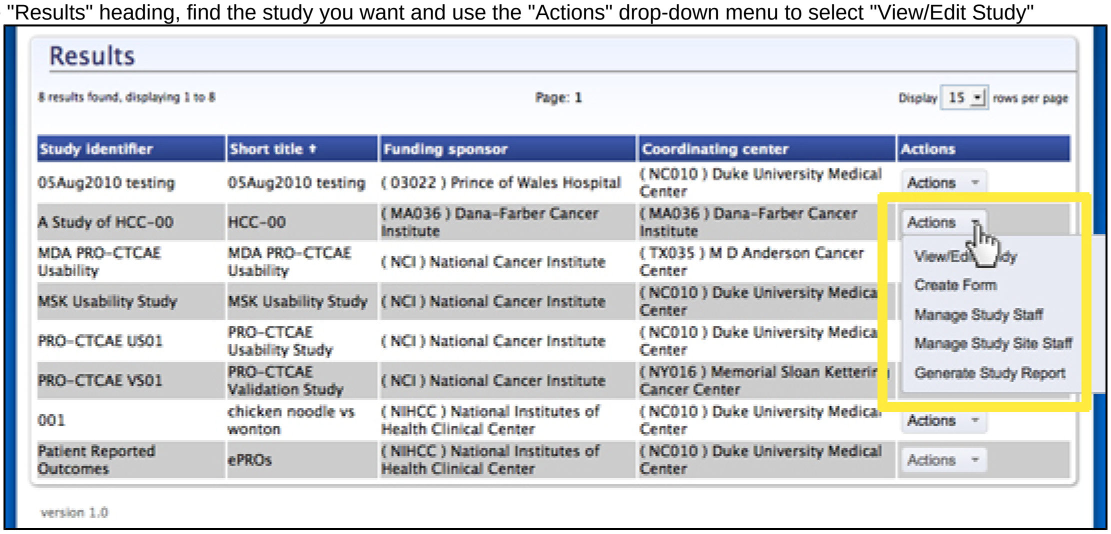
The Data Coordinator may view a study in PRO-CTCAE, and the Lead Site CRA, Lead Site PI, Site CRA, and Site PI may view and edit a study in PRO-CTCAE.
Hover over the "Studies" tab in the top navigation bar.

Click on "Manage Studies" in the lower navigation bar.



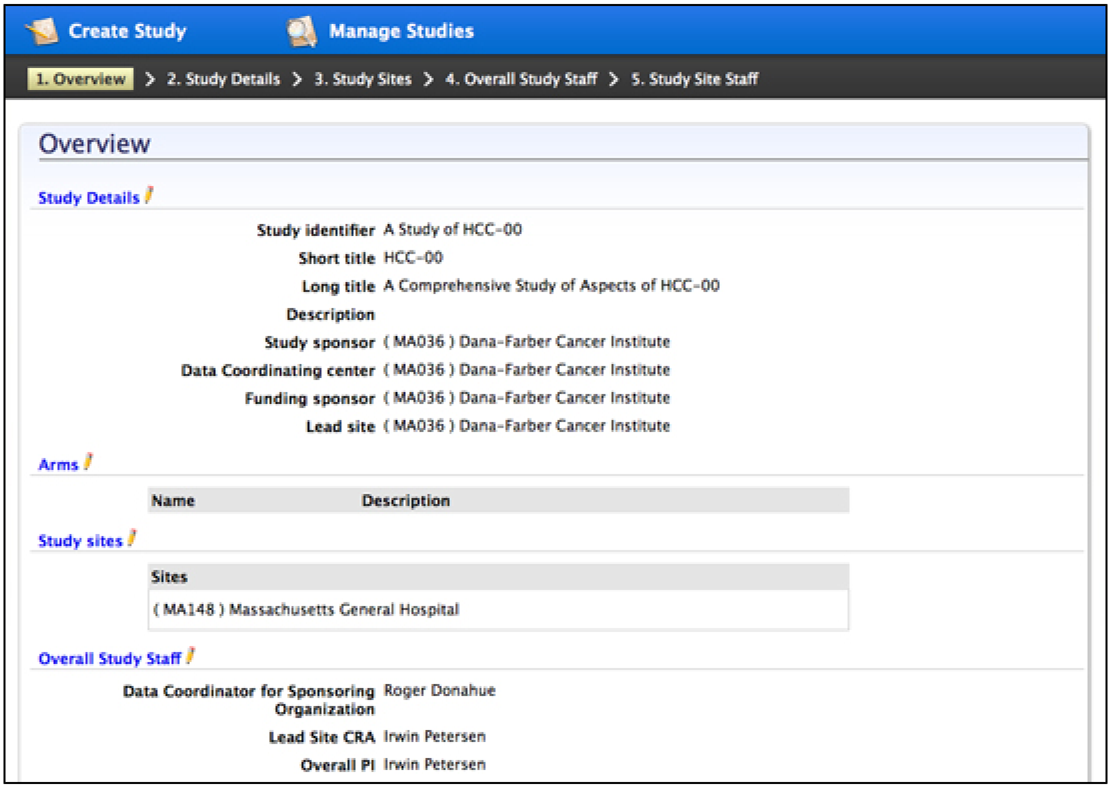
Search Criteria

1. Use the drop-down menu to search by short title or study identifier.
2. Enter the full short title or study identifier in the field.
3. Click on the blue "Search" button or hit the Enter key on your keyboard.
4. Under the "Results" heading, find the study you want and use the "Actions" drop-down menu to select "View/Edit Study"



Overview

This page shows an overview of information about this study, including "Study Details," "Arms," "Study Sites," "Overall Study Staff," and "Study Site Staff."



To make edits to a specific section, click on the blue section name or the pencil icon next to the section name. You may also click on the name of the section you want to edit in the black bar at the top of the page.

When you're done making edits to a section, you'll have three options:

1. Click on the blue "Save & Back" button on the bottom left of the screen to save your work and go to the preceding section (according to the order in the black bar at the top of the page).
2. Click on the blue "Save" button on the bottom right of the screen to save your work and return to the "Overview" screen.
3. Click on the green "Save & Continue" button on the bottom right of the screen to go to the next section.

After you've saved your work, you may skip to any section by clicking on the section you want in the black bar at the top of the page.

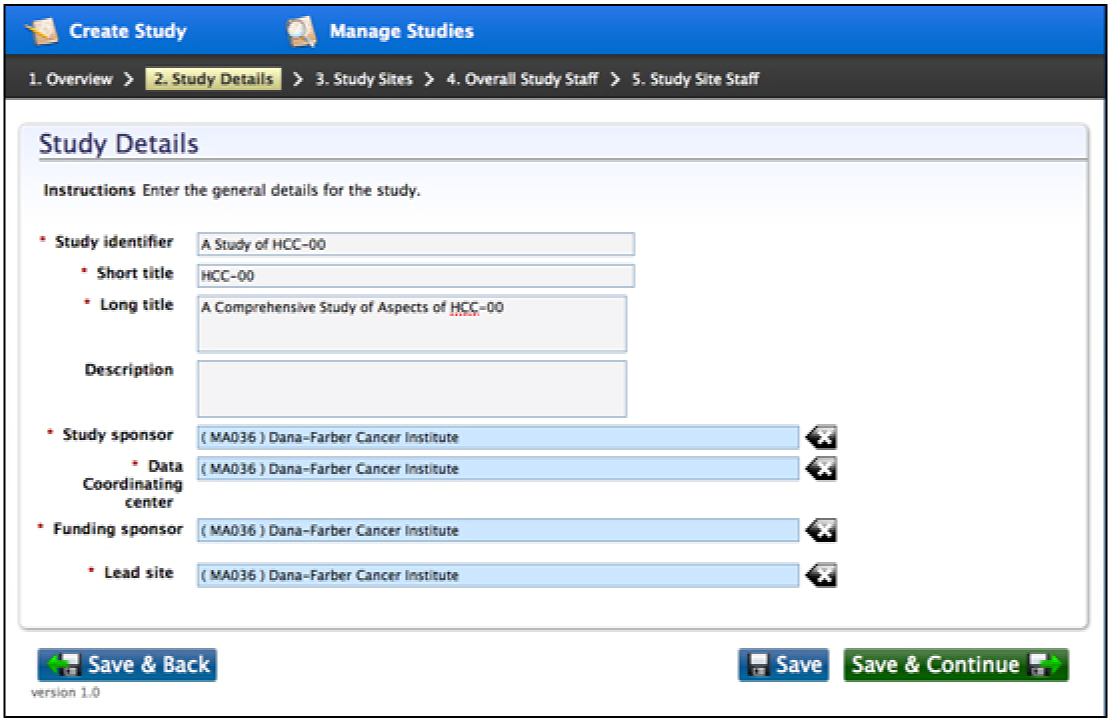
If you don't want to make edits to any section right now, click on the green "Continue" button on the bottom right of the screen.

Important

The Site CCA may view and edit study details in PRO-CTCAE.

Study Details

Here you will review the information that was provided about this study. You can make changes to any field. Fields noted with an asterisk are required.



You may add an arm to this study by clicking on the blue "Add" button at the bottom of the screen:

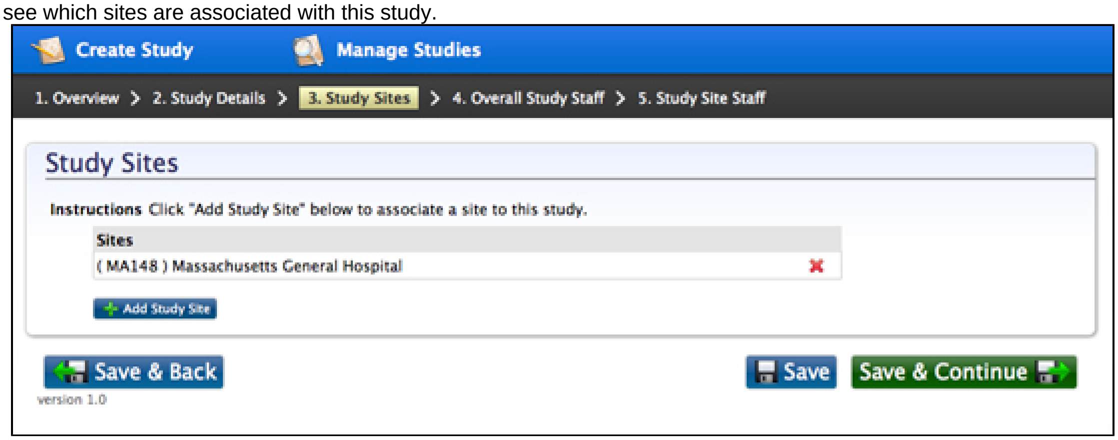
1. **Name:** Add the name of the arm here. This is a required field.
2. **Description:** You may also add a description for this arm here.
3. If you want to add another arm, click on the blue "Add" button again and repeat these steps. If you made a mistake and want to remove the arm, click on the red "X" next to this field.

You now have three options:

1. Click on the blue "Save & Back" button on the bottom left of the screen to save your work and return to the "Overview" screen.
2. Click on the blue "Save" button on the bottom right of the screen to return to the "Overview" section.
3. Click on the green "Save & Continue" button on the bottom right of the screen to save your work and go to the "Study Sites" section.

Study Sites

Here you will see which sites are associated with this study.



You may link additional sites to this study by clicking on the blue "Add Study Site" button at the bottom of the section:

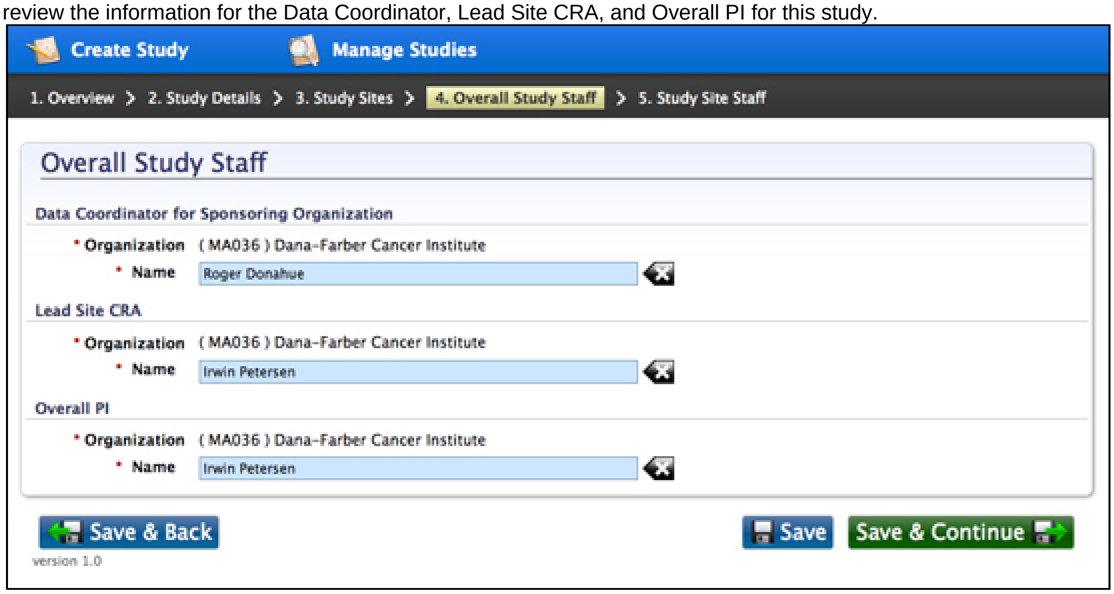
1. To enter the site, start typing its name. A drop-down menu will appear. Scroll down and click on the site you would like to add. If you choose the wrong one and want to clear the field, click on the white "X" in the small black icon.
2. Repeat these steps to add more sites.
3. You can delete any site by clicking on the red "X" next to the field. Note: You cannot delete a site if participants and clinical staff have been assigned to it.

You now have three options:

1. Click on the blue "Save & Back" button on the bottom left of the screen to save your work and go to the "Study Details" screen.
2. Click on the blue "Save" button on the bottom right of the screen to go to the "Overview" section.
3. Click on the green "Save & Continue" button on the bottom right of the screen to save your work and go to the "Overall Study Staff" section.

Overall Study Staff

Here you can review the information for the Data Coordinator, Lead Site CRA, and Overall PI for this study.



If you need to change the name of the Data Coordinator, Lead Site CRA, or Overall PI:

1. Click on the white "X" in the small black icon to clear the field.
2. Start typing his or her name. A drop-down menu will appear. Scroll down and click on the staff member you would like to add. (The staff member you are trying to add must already have a PRO-CTCAE account to appear in this drop-down list). If you choose the wrong name and want to clear the field, click on the white "X" in the small black icon.

Staff must be assigned to the role of Data Coordinator, Lead Site CRA, and Overall PI. If you delete a name, you must enter someone else in that field.

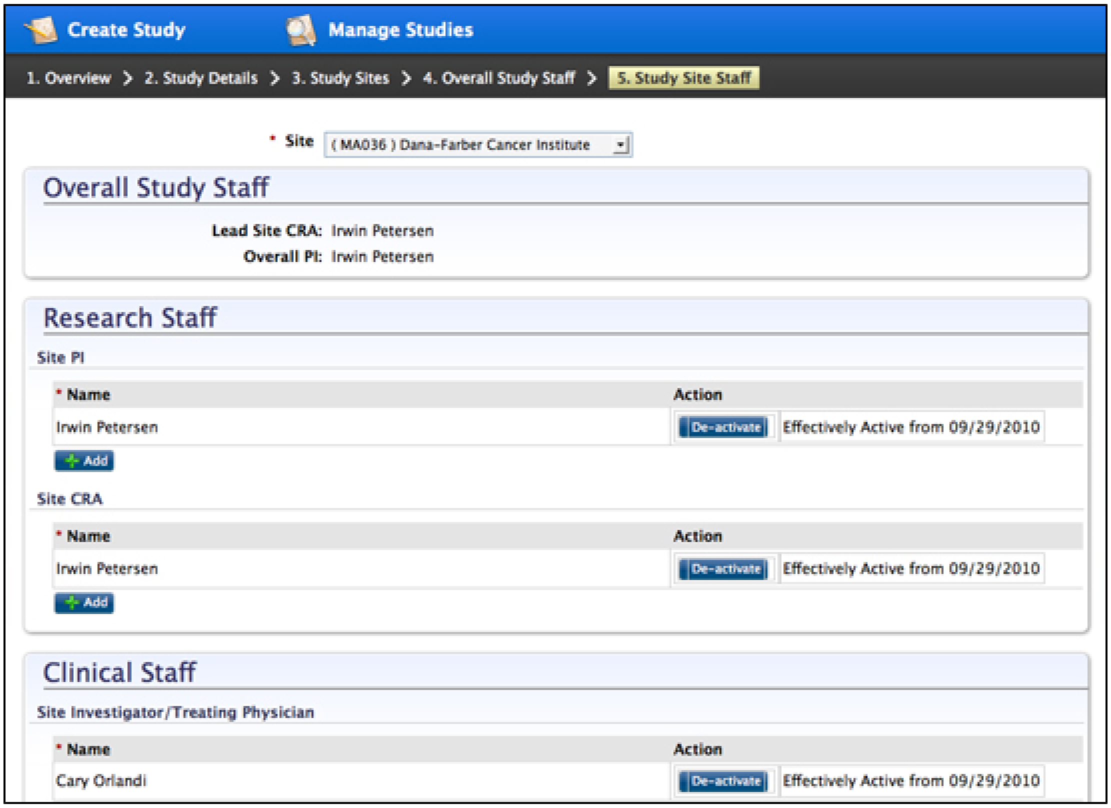
You now have three options:

1. Click on the blue "Save & Back" button on the bottom left of the screen to save your work and go to the "Study Sites" screen.
2. Click on the blue "Save" button on the bottom right of the screen to return to the "Overview" section.
3. Click on the green "Save & Continue" button on the bottom right of the screen to save your work and go to the "Study Site Staff" section. Note that only the Site CRA and the Site PI can proceed to this section.

Study Site Staff

Important

The Site CRA and Site PI may assign study site staff in PRO-CTCAE.
All fields are required (as noted with an asterisk). To associate staff members to each title, this individual must already have a PRO-CTCAE account to appear in the drop-down list:



Research Staff

Site PI: Click on the blue "Add" button. To enter the Site PI, start typing his or her name. A drop-down menu will appear. Scroll down and click on the name you would like to add. If you choose the wrong one and want to clear the field, click on the white "X" in the small black icon.

Site CRA: Click on the blue "Add" button. To enter the Site CRA, start typing his or her name. A drop-down menu will appear. Scroll down and click on the name you would like to add. If you choose the wrong one and want to clear the field, click on the white "X" in the small black icon. To designate more staff as Site CRA, click on the "Add" button and repeat the process. If you change your mind and decide that you don't want to add another Site CRA, click on the red "X" next to this field. [LS: You think there should be an option to make one of the site CRAs lead?]

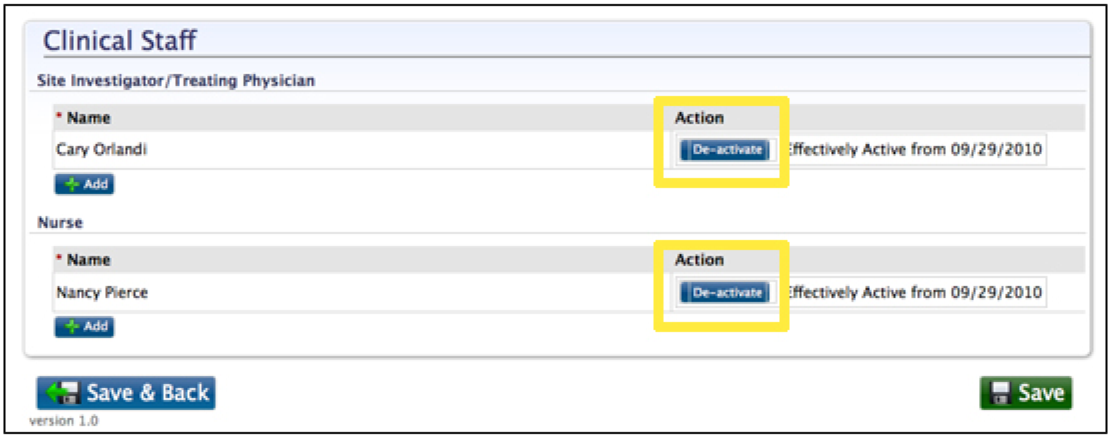
Clinical Staff

Site Investigator/Treating Physician: Click on the blue "Add" button. To enter the Site Investigator or Treating Physician, start typing his or her name. A drop-down menu will appear. Scroll down and click on the name you would like to add. If you choose the wrong one and want to clear the field, click on the white "X" in the small black icon. To designate more staff as Site Investigators, , click on the "Add" button and repeat the process. If you change your mind and decide that you don't want to add another Site Investigator or Treating Physician, click on the red "X" next to this field.

Nurse: Click on the blue "Add" button. To enter the Nurse, start typing his or her name. A drop-down menu will appear. Scroll down and click on the name you would like to add. If you choose the wrong one and want to clear the field, click on the white "X" in the small black icon. To designate more staff as study Nurse, click on the "Add" button and repeat the process. If you change your mind and decide that you don't want to add another Nurse, click on the red "X" next to this field.

If your study has more than one site associated with it and you want to add staff for another site before moving on, click on the blue "Save" button on the bottom right of the screen. Then use the drop-down menu at the top of the screen to select your next site. Scroll down and click on the site you want to add staff to. Repeat this process for as many sites as you want to work on.

If you want to change the date on which a staff person will become activated:



1. Click on the blue "Save" button on the bottom right of the screen first. This will cause blue "Deactivate" buttons to appear where the red "X" marks had been. Click on the "Deactivate" button for the staff person you want:
2. A dialog box will ask you to enter the date this staff person should be activated. Today's date will appear in the "Effective Date" field. To change it, type in the date in the mm/dd/yyyy format, or click on the calendar to choose the date. Click on "Submit" to set the activation date or "Cancel" if you decide you don't want to set a new activation date for this user.

You now have two options:

1. Click on the blue "Save & Back" button on the bottom left of the screen to save your work and return to the "Overall Study Staff" screen. Note that the page will return to Study Sites if the user is a Site CRA.
2. Click on the blue "Save" button on the bottom right of the screen to save your work and return later.